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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,938	06/04/2002	Shinichiro Morita	SAEG108.001APC	4758

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EXAMINER

NAFF, DAVID M

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 09/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/070,938

Applicant(s)

MORITA ET AL.

Examiner

David M. Naff

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/10&9/17/02</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1651

DETAILED ACTION

Claims examined on the merits 1-11 which are all claims in the application.

Claim Rejections - 35 USC § 103

5 The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

10 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15 This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation
20 under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

25 Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Naughton et al (5,863,531) in view of Vyakarnam et al (6,534,084 B1) taken with Hinsch et al (EP 0 274 898) (listed on form 1449) and Japanese patent 3-23864 (listed on form 1449).

Art Unit: 1651

The claims are drawn to a matrix for culturing cardiovascular cells to regenerate cardiovascular tissue comprising a sponge made of a bioabsorbable material and a reinforcement made of a bioabsorbable material. Also claimed is a method of culturing cardiovascular cells to regenerate cardiovascular tissue by seeding cells on the matrix and culturing the cells. The sponge has a pore diameter of about 5-100 μm .

Naughton et al disclose producing tissue *in vitro* by seeding cells on a three-dimensional structure having interstitial spaces which can be used to form tubular tissue structures (col 6, lines 55-60 and col 22, line 41) such as in the form of blood vessels (col 24, line 33), arteries (col 24, line 37) or veins (col 25, line 24). The three dimensional structure can be made of biodegradable material such as polyglycolic acid, polylactic acid or polyglycolic acid copolymer (col 9, lines 60-62). The three-dimensional structure can be made of a sponge (col 9, line 42).

Vyakarnam et al disclose foam structures that can be composed of copolymers of lactide such as a poly(L) lactide-co-E-caprolactone (col 6, line 45, col 9, lines 53-55 and col 12, lines 5-9), and which can be used to regenerate tissue such as tubular structures such as vascular grafts (col 3, lines 1 and 20-21, and col 9, lines 19-24). The pore size of the foam can be 30-50 μm or 100-200 μm (paragraph bridging cols 4 and 5). The foam can be reinforced with fibers (col 6, line 40).

Art Unit: 1651

Hinsch et al disclose a porous implant having a pore size of 10-200 μm for the growth of blood vessels in the form of a foam made of a resorbable polymer such as a copolymer of glycolide and lactide (page 4, lines 1-8). The foam may contain textile reinforcing elements such as fibers or knitted fabrics (page 3, lines 8-13).

The Japanese patent discloses a reinforced collagen sponge for implanting in tissue. The sponge is reinforced with fibers made of poly-L-lactic acid.

It would have been obvious to form the biodegradable polyglycolic acid copolymer tubular structures of Naughton et al with the biodegradable foam of Vyakarnam et al that is a copolymer of glycolide and lactide since this foam can be used for producing a tubular structure and has advantageous properties. It would have been further obvious to reinforce the foam with fibers as suggested by Hinsch et al and the Japanese patent using fibers to reinforce a foam implant. It would have been obvious to use fibers formed of poly-L-lactic acid as taught by the Japanese patent so that both the foam and fibers are bioabsorbable. Using polyglycolic acid as in claim 4 to form the fibers would have been a matter of obvious choice. A foam as disclosed by the references is a sponge. When forming the tubular structures of Naughton et al, cardiovascular cells are used and the tissue produced is cardiovascular tissue. The conditions of dependent claims would have been obvious from the disclosures of the references. Structures other than tubular structures such as a cardiac valve or pericardium as in certain dependent claims would have been obvious

Art Unit: 1651

from the many different structures disclosed by Naughton et al. Using two or more different cells as in claim 11 would have been obvious from Naughton et al using different types of cells together.

Conclusion

5 Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful,
10 the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR)
15 system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private
20 PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David M. Naff
Primary Examiner
Art Unit 1651